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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/802,996

03/17/2004

Michael M. Meguid

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EXAMINER

HAMA, JOANNE

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 07/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/802,996	Applicant(s) MEGUID, MICHAEL M.	
	Examiner Joanne Hama, Ph.D.	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 May 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 9-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 19, 2006 has been entered.

Applicant has filed amended claims on May 19, 2006. While there is a listing of claims 1-8, claims 9-24, withdrawn claims, are missing. This is not in compliance with MPEP 714. Applicant must comply with the rules set forth in the MPEP or risk not having amendments entered. In the interest of expediting prosecution, an action of the merits has been carried out as follows.

Maintained Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 5-7 are rejected in modified form under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for

1) a surgically modified wild-type non-human mammal, comprising a preoperative weight and a preoperative endogenous ghrelin production and a gastrointestinal tract that has undergone a surgical modification, wherein said surgical modification reduces the volume of a stomach of said gastrointestinal tract, and wherein postoperatively, said surgically modified non-human mammal exhibits permanent reduction of said preoperative weight and permanent reduction of preoperative endogenous ghrelin production and

2) a surgically modified Zucker rat, comprising a preoperative weight and a preoperative endogenous ghrelin production and a gastrointestinal tract that has undergone a surgical modification, wherein said surgical modification reduces the volume of a stomach of said gastrointestinal tract, and wherein postoperatively, said surgically modified non-human mammal exhibits permanent reduction of said preoperative weight and permanent reduction of preoperative endogenous ghrelin production,

does not reasonably provide enablement for

1) surgically modified non-human mammals that are
already existing transgenic murine, ovine, porcine, caprine, canine, feline, and primate non-human mammals,

already existing genetically modified murine, ovine, porcine, caprine, canine, feline, and other non-human mammals,

already existing cloned murine, ovine, porcine, caprine, canine, feline, and non-human mammals,

wherein said surgically modified non-human mammals comprise a preoperative weight and a preoperative endogenous ghrelin production and a gastrointestinal tract that has undergone a surgical modification, wherein said surgical modification reduces the volume of a stomach of said gastrointestinal tract, and wherein postoperatively, said surgically modified non-human mammal exhibits permanent reduction of said preoperative weight and permanent reduction of preoperative endogenous ghrelin production.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Applicant's arguments filed May 19, 2006 have been fully considered but they are not persuasive.

Applicant has amended the claims to address the issue of the claims encompassing the broad scope of any transgenic, genetically modified, or cloned non-human mammals. While Applicant has amended the claims to indicate that the claimed mammals are ones that are "already existing," the specification only teaches the Zucker rat. The Zucker rat is not representative of the broad scope of all non-human transgenic, genetically modified, and cloned non-human mammals and thus does not enable an artisan to use the broad scope of any transgenic, genetically modified, and cloned non-human mammals. Should Applicant wish to claim more than the Zucker rat, teachings of the art indicating the existence of these non-human mammals should be provided.

Thus, the claims remain rejected.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-8 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for reasons of record, March 14, 2005 and January 11, 2006.

Applicant's arguments, see pages 8-9 of Applicant's response, filed May 19, 2006, with respect to the rejection of claims 1-8 have been fully considered and are persuasive in part. Applicant has amended the specification and claim 1 to remove the term "substantially" to describe "normal," The Examiner has found this amendment persuasive to withdraw the rejection as it applies to "substantially normal." However, "substantially" is used to describe "permanent reduction" (claim 1, lines 8-9). "Substantially" is a relative term and its metes and bounds are unclear.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 7, 8 remain rejected under 35 U.S.C. 102(b) as being anticipated by Young et al., 1984, The American Journal of Clinical Nutrition, 40: 293-302, for reasons of record, March 14, 2005 and January 11, 2006.

Applicant's arguments filed May 19, 2006 have been fully considered but they are not persuasive.

Applicant indicates that the specification and the claims have been amended to limit the claimed surgical modification to a nonhuman mammalian animal and to one in which the claimed surgical modification reduces (but does not eliminate) the volume of a functional stomach into which food enters and in which food is lodged while undergoing digestion in the stomach (Applicant's response, page 11). In response, while Applicant has amended the claims, Young et al.'s teachings remain readable on the amended claims, as Young et al. teach Zucker rats that comprise Roux-en-Y gastrojejunostomy. While Applicant has amended the claims, the claim amendment does not appear to distinguish the claimed invention from Young et al.

As such, the claims remain rejected.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joanne Hama, Ph.D. whose telephone number is 571-272-2911. The examiner can normally be reached Monday through Thursday and alternate Fridays from 9:00-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

JH

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER

